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June 2, 2006

Docket No. APHIS-2005-0103  
Regulatory Analysis and Development  
PPD, APHIS, Station 3A-03.8  
4700 River Road, Unit 118  
Riverdale, MD 20737-1238

**RE: Docket No. APHIS-2005-0103**

Please accept the following comments and recommendations from the **National Plant Board**.

Docket No. APHIS-2005-0103 proposes regulations “to establish a process by which a State or political subdivision of a State could request approval to impose prohibitions or restrictions on the movement in interstate commerce of specific articles that are in addition to the prohibitions and restrictions imposed by the Animal and Plant Health Inspection Service.”

1. The National Plant Board (NPB) commends USDA-APHIS for initiating this proposed rule which will provide standards and procedures for ‘special need’ requests while deterring the imposition of local regulations that are biologically and scientifically unsound.

**2. Definitions:**

Definitions for the following terms do not appear in the Plant Protection Act and should be included in the proposed rule.

(a) ***Special Need.*** The demonstrated existence of an unacceptable level of pest threat or harm that justifies the imposition of interstate movement prohibitions or restrictions by a state or political subdivision of a state, in addition to federal prohibitions or restrictions already in place.

(b) ***Sound Scientific Data.*** Factual biological, climatic or weather, pest and host presence/absence and distribution, and other special need relevant information gathered from existing scientific literature or generated by professional scientists.

Some relevant international standards, for example, are the Food and Agriculture Organization’s International Standards for Phytosanitary Measures: # 01, “Principles of Plant Quarantine As Related to International Trade”; # 03, Guidelines for the Export, Shipment, Import and Release of Biological Control Agents and Other Beneficial Organisms”; # 14, “The Use of Integrated Measures In A Systems Approach for Pest Risk Management”; and # 24, Guidelines for the Determination and

Recognition of Equivalence of Phytosanitary Measures.”

(c) **Thorough Risk Assessment.** The analysis and evaluation of existing sound scientific evidence relevant to a specific special need request and generally in accordance with nationally and internationally accepted standards to determine the level of quarantine pest risk and whether pest threat or harm justifies the imposition of prohibitions or restrictions by a state or political subdivision of a state, in addition to federal prohibitions or restrictions already in place.

Relevant national standards include, “National Plant Board Plant Quarantine, Nursery Inspection and Certification Guidelines” and “USDA Guidelines for Pathway-Initiated Pest Risk Assessments.” Some relevant international standards, for example, are the Food and Agriculture Organization’s International Standards for Phytosanitary Measures: # 02, “Guidelines for Pest Risk Analysis” and # 11, “Pest Risk Analysis for Quarantine Pests Including Analysis of Environmental Risks and Living Modified Organisms.”

(d) **Scientifically Sound Detection Survey.** A systematic search for a specific organism that is performed in accordance with established, relevant national and international standards.

Some relevant international standards, for example, are the Food and Agriculture Organization’s International Standards for Phytosanitary Measures: # 05, “Glossary of Phytosanitary Terms”; # 06, “Guidelines for Surveillance”; and # 08, “Determination of Pest Status in An Area.”

### 3. Criteria for special need requests:

The proposed rule does not address the level of rigor that USDA expects as adequate, relative to the five criteria for special need requests. Thus, considerable variation in the USDA evaluation process may occur (one petition might be approved, while another of equal rigor is rejected). The ‘Special Need’ Criteria document submitted by the National Plant Board (NPB) to the USDA in 2003 commented as follows on the issue of rigor:

*“Criteria for state-conducted pest risk assessments will need to conform in a reasonable manner to existing international requirements because standards will be established by USDA to address state petitions pursuant to the ‘Special Needs’ provision of the PPA..... However, the level of detail reached in any risk assessment is dependent upon the amount of information available and the resources available to gather and use that information. For many pests, particularly those considered new or recent introductions, only limited information is available with which to create risk assessments. For many states, resources are a limiting factor in collecting and analyzing information to satisfy a ‘Special Need’ request. The criteria set forth for such a request need only be as complex as is technically justified by circumstances, based on necessity, minimal impact, transparency, equivalence, analysis and risk.”*

**Relative to risk assessment, the NPB 2003 document submitted the following criteria which we support and advocate:**

*“‘Sound scientific data’ or a ‘thorough risk assessment’ must be provided. This may be limited to only those risk elements/impacts not adequately mitigated by federal restrictions or actions. Pest effects may be direct or indirect, affecting commercial markets, trade restrictions, qualitative environmental consequences, etc. Qualitative as well as quantitative pest risk information based on*

*probabilities for entry, establishment, spread and economic/environmental outcome may be used. Scientific or risk assessment data may include information relative to:*

- (1) Identification of a new pest of quarantine concern.*
- (2) Pest presence/absence and/or distribution.*
- (3) Detection and eradication potential capabilities.*
- (4) Entry potential (pathway holes, conditions at origin or en route).*
- (5) Potential for colonization and spread including basic pest biology, host presence and abundance, favorable climate, commodity dissemination, means of natural spread once introduced, existing control measures, etc.*
- (6) Economic impacts including lowered yields, increased production costs, control costs, potential imposed quarantines, adversely affected markets and profitability, etc.*
- (7) Social and environmental impacts including adverse effects on human health, food safety, lifestyles, employment, natural resources, native species, habitats, increased pesticide use, etc.*
- (8) Citations for all references used in the development of the state's justification."*

In some cases, the tools available for detection and delimitation surveys might be meager, at best. This must be taken into consideration. Obviously, what the USDA expects should not exceed the level of survey used by the USDA to justify its own federal domestic quarantine.

**We recommend that criteria for special need request approval be included to clarify expectations and eliminate the possibility for arbitrary or capricious evaluations. The criteria contained in the NPB 2003 document seem appropriate:**

- (a) The prohibitions or restrictions must be clearly identified.*
- (b) The pest(s) and/or pathway(s) must be clearly identified. The associated risk(s) or threats not adequately mitigated by existing federal restrictions or actions must be identified and described. Factors for consideration may include:*
  - (1) New commodity, new pest, new pathway or new plant species introduction.*
  - (2) Probability of damage or harm in excess of what might occur in other states.*
  - (3) Pest interception data demonstrating inadequacy of mitigation by federal quarantine.*
  - (4) The existence of new or special pest risk element/impacts.*
  - (5) Inadequate federal mitigation of risks.*
  - (6) National Plant Board comments on Docket No. APHIS–2005–0103*

#### **4. Action on special need requests:**

There is no absolute timeline identified in the proposed rule for publication, review and comment, or final decision. The general timelines proposed are far too long, given a) the reasonable amount of time expected for the USDA to complete its evaluation of the data submitted by the petitioning state, and b) the time required to publish a proposed rule in the Federal Register.

**We recommend that the USDA commit to:**

**No more than 30 days for completion of its review;**

**No more than 15 days for public comment;**

**No more than 30 days for a final decision following the closing of the comment period.**

June 2, 3006

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Given these timeframes, the whole process will take an absolute minimum of 60 to 75 days from receipt of the petition to final rule publication. Special need requests typically will be based on an immediate need or emergency situation. Any delays in processing, reviewing or decision-making will extend the risk associated with the pest concern.

The NPB appreciates the opportunity to comment on Docket No. APHIS–2005–0103. In closing, we commend the USDA's proposal to establish criteria governing state petitions for the imposition of special need requirements. Please feel free to contact me relative to any questions raised by our comments or other information that might be needed.

Sincerely,

A handwritten signature in black ink, appearing to read "Kenneth J. Rauscher", is written over a light gray rectangular background.

Kenneth J. Rauscher, President  
National Plant Board